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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/099,698	06/18/98	FRANZ-BACON K	DA/0187

HM32/0809

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EXAMINER	
DRAPER, G	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 08/09/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

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SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/099,898	06/18/98	FRANZ-BACON K	DX0744K

HM32/0120

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EXAMINER	
ART UNIT	PAPER NUMBER
1646	6

DATE MAILED: 8.9.99

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

For Restriction only

☒ This application has been examined ☐ Responsive to communication filed on _____ ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 1 month(s), 30 days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☐ Notice of References Cited by Examiner, PTO-892.
2. ☐ Notice of Draftsman's Patent Drawing Review, PTO-948.
3. ☐ Notice of Art Cited by Applicant, PTO-1449.
4. ☐ Notice of Informal Patent Application, PTO-152.
5. ☐ Information on How to Effect Drawing Changes, PTO-1474.
6. ☐ _____.

Part II SUMMARY OF ACTION

1. ☒ Claims 1-18 are pending in the application.
   Of the above, claims _____ are withdrawn from consideration.
2. ☐ Claims _____ have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☐ Claims _____ are rejected.
5. ☐ Claims _____ are objected to.
6. ☒ Claims 1-18 are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____. has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed _____, has been ☐ approved; ☐ disapproved (see explanation).
12. ☐ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____ ; filed on _____.
13. ☐ Since this application apppears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

EXAMINER'S ACTION

PTOL-326 (Rev. 2/93)

1.Part III: Detailed Office Action for Restriction

2. Restriction Requirement:

First, Please Note: In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A **dedicated** Fax machine is in place to receive your responses. The Fax number is 703-305-3704. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Paula Hutzell, Ph.D., Supervisory Patent Examiner at 703-308-4310. Thank you in advance for allowing us to enhance our customer service. **Please limit the use of this dedicated Fax number to responses to Written Restrictions.**

No attempt was made to call for an oral election from Ed Ching because Mr. Ching had informed the Examiner in previous calls regarding applications by the Assignee that oral elections would not be possible and that the restrictions should be issued in writing.

3. First of all, in reference to this written restriction, it is pointed out that the claims have been presented in very poor format and constitute an improper Markush format **and some possibly constitute improper composition claims for the various protein** products, their fragments and fusion products, as well as the various method claims. In those instances where there are multiple products or methods that are presented in the improper Markush format, each of the products and the methods are clearly patentably distinct, wherein independent or separate claims should have been presented for each of these separate products and to the separate methods. But more preferably these distinct products should have been filed in separate applications as totally distinct products. Furthermore, many of the claims also list identifying characteristics as well as alternative embodiment/claim limitations (such as those listed in the subparts of a, b, c, d, e, f, g, h, I, etc) that really should not appear collectively in one claim in this format. Consequently, applicant's claims are considered prolix because they contain long recitations or unimportant details which hide or obscure the invention; or they recite very long detailed claims setting forth so many elements that the invention cannot possibly reside in the combination and should be rejected as prolix [See *Ex parte Iagan*, 1911 C.D. 10, 162 O.G. 538 (Comm'r Pat. 1910); and *In re Ludwick*, 4 F.2d 959, 1925 C.D. 306, 339 O.G. 393 (D.C. Cir 1925) respectively].

Additionally, the format of many of the claims comprise double inclusion of an element in members of a Markush groups, where there is overlapping members for alternatives recited in a claim's Markush groups, or where the claim can be read to include the same element twice [For support see *Ex parte White*, 759 O.G. 783 (Bd App 1958; *Ex parte Clark*, 174 USPQ 40 (Bd App. 1971; *Ex parte Kristensen*, 10 USPQ2d 1701 (Bd. Pat. App. & Inter. 1989)] This causes the claims to be objectionable and indefinite.

Finally, the claims represent undue multiplicity/an unreasonable number of claims or claim

limitations, that are unreasonable in view of the nature and scope of applicants's invention and the state of the art, inasmuch as it relates to confusion of the issue. The Examiner recognizes that there may not be a large number of claims, but this is because applicants have chosen to combined many of these distinct products and/or limitations/embodiment into one claims. However, the issue is still the same, which makes this consistent with the CCPA's position set forth in In re Chandler, 254 F.2d 396, 117 USPQ 361 (1959) and In re Chandler, 319 F.2d 211, 225, 135 USPQ 138, 148 (1963) where it was held that applicant's latitude in stating their claims in regard to number and phraseology employed "should not be extended to sanction that degree of repetition and multiplicity which beclouds definition in a maze of confusion"). Furthermore, such claims, or claim limitations or permutations could be rejected one over the other if they differ only by subject matter old in the art (*Ex parte Whitelaw*, 1915 C.D. 18, 219 O.G. 1237 (Comm'r Pat. 1914), where this doctrine is applied when the claims are unduly multiplied or are substantial duplicates (*Ex parte Kochan*, 131 USPQ 204, 206 (Bd. App. 1961).

Additionally, certain sub-parts of the claims are directed to a kit, and it is not clear if the compositional make-up of the claims are intended to reflect a kit to the protein, antibody, nucleic acids or a combination of these products. Further, if applicant really intend to have claims to a proper kit and the claims are properly amended to reflect such (multiple elements and physical features to properly define a kit), then these claims to the distinct products may be restricted out from the recited product that they are presently grouped with.

The poor format of applicant's claims **also** causes the written restriction and first office actions on the merits to be extremely long because the Examiner has to constantly point out numerous defects in claim language, format, and claim limitations. However, despite such, the restriction will be set forth as best as reasonably possible and relative to these distinct products as, irrespective of whether these products or methods represent claim designation of 1a, 1b, 1c, 1d etc. The format in which the claims are written has made it difficult to reasonably separate these groups and has caused the claims to be directed to several inventive groups that will be shown to be patentably distinct. Because of the numerous Groups, which causes this written restriction to be very very long, the groups and reasons for distinction will be set forth in an abbreviated format. Furthermore, when the election is made, applicant's patent counsel is advised to **please** present amended claims that are only directed to a single product-if the election is to a product rather than a single method, and further should be amended to avoid the kind of rejects for the numerous issues that have been set forth above.

The Assignee's patent counsel has been advised of this on numerous times in other applications, but has no complied by presenting claims in better and a proper format. The Examiner has also had telephone conversation with the Patent Counsel to further point out the problems with such applications and the claims so that many of the problems that exist with the claims can be avoided with the filing of more appropriate claims in subsequent applications. The Examiner has also suggested more appropriate claim's language in other applications, but this can not be continuously done in the various office actions issued by the Examiner, as many of these defects are things that the Patent Counsel should not have made, and should correct, based on the constant urging of this Examiner.

ALL OF THIS IS BEING POINTED OUT AT THIS TIME SO THAT APPLICANTS CAN CORRECT THE VERY OBVIOUS ERRORS; SO AS TO ISSUE AN OFFICE ACTION ON THE MERITS OF WHAT IS INTENDED BY THE CLAIMED INVENTION; AND SO AS TO REDUCE THE TIME FOR COMPLIANCE OF THESE ISSUES AND TO ADVANCE PROSECUTION.

Restriction to one of the following inventions is required under 35 U.S.C. 121

I. Claims 1a, 1b, 2-4, 5a and 6 are drawn to a protein, C23 and presumably a compositions and/or kit thereto, 530/351, and 424/85.1 , 435 or 436-depending on whether the kit is a composition or a true kit, as discussed above.

II. Claims 1c, and 5b are drawn to fusion proteins of the protein with an Ig, 530/387.2 or the subclass varies depending on the nature of the other generic fusion partner.

III. Claims 1c, and 5c are drawn to fusion proteins of the protein with another cytokine, 530/351+ or the subclass varies depending on the nature of the other generic fusion partner.

IV. Claims 3b(xiv), drawn to protein conjugate, 530/351+ or the subclass varies depending on the nature of the other chemical moiety.

V . Claims 7-10 are drawn to antibodies, classified in classes 530/388.23 or 424/85.1 or 435, or 436-subclass varies, respectively depending on whether the kit is a composition or a true kit, as discussed above.

VI. Claims 11-17 are drawn to nucleic acids encoding the protein, **methods of recombinant production of such**, 536/23/5 or 514/44 or 435/69.5+, respectively depending on whether the kit is a composition or a true kit, as discussed above.

VII. Claim 18 drawn to a method of using an antagonist, classified in class 424, 514, or 435, subclass vary depending on the nature of the antagonist and whether the method is in vivo or in vitro.

VIII. Claim 18, drawn to a method of using an agonist, classified in class 424, 514, or 435, subclass vary depending on the nature of the antagonist and whether the method is in vivo or in vitro.

The inventions are distinct, each from the other because:

Inventions of Group I and Group VI are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). It is pointed out that the protein can be made by a materially different process other than with the use of the nucleic acid, vectors and host cells. Furthermore, the protein of Group I and the Nucleic acid, vectors, and host cells of Group VI represent products that are structurally, physically, functionally, and if determined to be patentable, they would also be patentably distinct. Furthermore, the nucleic acids can be used other than to make the protein, such as their use therapeutically, diagnostically, or to make transgenic animals.

Inventions Group I and Group II-->V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). Although there is no pro se method for using the protein, in the instant case the protein as claimed can be used in a materially different process, such as its use in various therapeutic methods, or its use in other diagnostic methods such as affinity chromatography, or it could be used to make the antibodies or used as a probe.

It is further pointed out that although there are no provisions under the section for "Relationship of Inventions" in MPEP 806.05 for multiple/different products, restriction is deemed to be proper because the products appear to constitute patentably distinct inventions. The inventive products of Groups I, II, III, IV, V, and VI are directed to products that are structurally, physically and functionally distinct and if determined to be patentable they would also be patentably distinct. Furthermore, these products are not required one for the other, nor is each of the products used in each of the methods.

In a similar manner it is further pointed out that although there are no provisions under the section for "Relationship of Inventions" in MPEP 806.05 for multiple/different methods, restriction is deemed to be proper because the methods appear to constitute patentably distinct inventions. The inventive methods of Groups VI--->VIII require the use of different steps/methods; elements/agents that are physically and functionally distinct; there are different starting elements and the final outcome/results are different for these different methods that cover various diagnostics and therapeutic methods; and if determined to be patentable they would also be patentably distinct. Furthermore, these methods are not required one for the other, nor does each of the methods require the use of each of the products.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classifications which are not co-extensive. And there are different issues for the search and examination of each group, which would be

unduly burdensome, accordingly, restriction for examination purposes as indicated is proper.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

3. ***Advisory Information:***

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to **Garnette D. Draper, Art Unit 1646, whose telephone number is (703) 308-4232.** Examiner Draper can normally be reached Monday through Friday, 9:30 A.M. to 6:00 P.M.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist at telephone number (703) 308-0196.

Official papers filed by fax for this "Pilot for Written Restrictions" should be directed to (703) 305-3704-which is a Fax machine specifically for this pilot. Papers related to this application for election from the written restriction may be submitted to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. **NO DUPLICATE COPIES SHOULD BE SUBMITTED** so as to avoid the processing of duplicate papers in the Office.

GARNETTE D. DRAPER
PRIMARY EXAMINER
GROUP 1800